ISRCTN70913605 https://doi.org/10.1186/ISRCTN70913605

Complete Versus Lesion-only Primary PCI Pilot Study

Submission date 01/02/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/02/2011	**Overall study status** Completed	
Last Edited 13/06/2016	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
A heart attack happens because the coronary artery becomes blocked. If this block is not relieved within a certain time from the onset of symptoms then irreparable heart muscle damage occurs, which will impact on the patient's future prognosis. The standard of care for patients suffering heart attacks is to rush them to the catheter lab and use a wire, balloon and stent to open up and retain the lumen to restore blood flow (percutaneous coronary intervention [PCI]). In about 30% of patients other narrowings are found at the time of the procedure. Knowing what to do with these narrowings has become a contentious and hotly debated issue. Previous research suggests that the narrowing should not be treated, but a recent trial suggested there was benefit from treating them.

Who can participate?
Patients with suspected or proven acute myocardial infarction scheduled for PCI for clinical reasons.

What does the study involve?
Patients found to have narrowings in non-heart attack causing arteries were randomly allocated to one of two groups. One group was treated by opening the artery that was causing the heart attack and so restoring flow but not treating any other narrowings in other arteries. For the other group both the blocked artery and any noted significant narrowings were treated.

What are the possible benefits and risks of participating?
The risks of participating are not significant since the current standard of care is to undertake angioplasty on the artery causing the heart attack.

Where is the study run from?
University Hospitals of Leicester (UK)

When is the study starting and how long is it expected to run for?
April 2011 to May 2014

Who is funding the study?
British Heart Foundation and Medical Research Council (MRC)/National Institutes of Health Research (NIHR) (UK)

Who is the main contact?
Prof Anthony Gershlick

Contact information

Type(s)
Scientific

Contact name
Prof Anthony Gershlick

Contact details
Professor of Interventional Cardiology
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V 1.1 30th Sep 2009; EME 10-27-01

Study information

Scientific Title
A study of patients with multi-vessel disease presenting with acute myocardial infarction undergoing primary percutaneous coronary intervention (PPCI) including a prospective registry of all PPCI patients and a pilot study in a subset of patients with multi-vessel coronary disease randomised to a strategy of early multi-vessel revascularisation or infarct related artery revascularisation only

Acronym
CVLPRIT

Study objectives
The CVLPRIT study is made up of two parts, the observational registry of all percutaneous coronary intervention (PPCI) patients (REGISTRY) admitted to the participating hospitals and a randomised controlled trial in those with multivessel coronary disease (RCT).

The main research questions for the two parts are:
1. Registry: What is the proportion of patients with heart attacks who undergo PPCI who also have multivessel disease (more than one coronary artery blocked or narrowed).
2. Randomised controlled trial: In patients with multivessel disease to compare the feasibility, safety and prognosis of a strategy of "complete" early coronary revascularisation (i.e. opening all blockages and narrowings of the coronary arteries) with a "culprit" lesion only strategy (only open the coronary artery causing the heart attack).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent Research Ethics Committee, 21/01/2011, ref: 11/H0405/4

Study design
Prospective observational registry and open multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
ST elevation myocardial infarction (STEMI)

Interventions
Primary percutaneous coronary intervention in patients with multi-vessel coronary disease randomised to a strategy of early multi-vessel revascularisation or infarct related artery revascularisation only. The randomised patients will be followed up for 12 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Cumulative major adverse cardiovascular events (MACE): all-cause mortality, recurrent MI, heart failure, need for revascularisation (PCI or CABG), measured up to 12 months

Secondary outcome measures
1. Individual components of primary composite outcome
2. Safety: Emergency coronary artery bypass graft (CABG), confirmed stroke, major bleeding,

surgical repair of vascular complications, up to 12 months
3. Number of patients presenting with PPCI with significant micro vessel density (MVD)
4. Ischaemic burden at 6-8 weeks (expressed as % of total) by MPS
5. Economic assessment and cost efficacy including days in hospital at 12 months
6. Contrast induced nephropathy (rise Cr greater than 25%) or 44.2 umol/l within 48 hours persisting greater than or equal to 48 hours
7. Change in NT-ProBNP from pre-discharge to 12 months
8. Echocardiographic left ventricular ejection fraction (LVEF) and wall motion score (discharge and 12 months)
9. Quality of Life Score at 12 Months (EuroQol questionnaire)
10. Infarct size, extent of microvascular obstruction, myocardium salvaged, left Ventricular (LV) volumes and ejection fraction (EF) at discharge by CMR and new myocardial injury and volumes at 9 - 12 months

Overall study start date
01/04/2011

Completion date
30/05/2014

Eligibility

Key inclusion criteria
Registry:
1. Suspected or proven acute myocardial infarction
2. Significant ST elevation on electrocardiogram (ECG)
3. Less than 12 hours of symptom onset
4. Scheduled for primary percutaneous coronary intervention (PCI) for clinical reasons
5. Provision of verbal assent followed by written informed consent

RCT:
1. Suspected or proven acute myocardial infarction
2. Significant ST elevation on ECG
3. Less than 12 hours of symptom onset
4. Scheduled for Primary PCI for clinical reasons
5. Provision of verbal assent followed by written informed consent
6. Multivessel coronary disease detected at time of angiography

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Registry: 1000 participants, RCT: 296 participants

Key exclusion criteria

Registry:
There are no formal exclusion criteria for the CVLPRIT registry for patients that meet the inclusion criteria.

RCT:
1. Any contraindication to PPCI or multi-vessel PPCI
2. Less than 18 years age
3. Clear indication for or contraindication to multivessel PPCI, according to operator judgement and the reasons will be documented
4. Severe kidney impairment

Date of first enrolment
01/04/2011

Date of final enrolment
30/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
Trust Headquarters, Level 3
Balmoral Building
Leicester Royal Infirmary
Infirmary Square
Leicester
England
United Kingdom
LE1 5WW

Sponsor type

Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK) (ref: SP/10/001/28194)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Medical Research Council (MRC)/National Institutes of Health Research (NIHR) (UK) - Efficacy and Mechanism Evaluation (EME) Programme (ref: EME 10-27-01)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/03/2015		Yes	No
Results article	results	22/12/2015		Yes	No
Results article	results	01/01/2016		Yes	No
Results article	results	31/05/2016		Yes	No
Results article	results	01/06/2016		Yes	No